510(k) SUMMARY

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December 26, 2011

Name of Device:

Trade Name:	Kaneka Trimotion™ Injector
Common/Usual Name:	Disposable corneal tissue transplant injector
Proposed Classification Name:	Intraocular Lens Guide 21 CFR 886.4300 (OTZ) Class I reserved

Predicate Device:

The predicate device is the Ocular System Inc. EndoSerter™ corneal endothelium delivery instrument (510(k) No. K090626), cleared by the Food and Drug Administration on January 21, 2011.

Device Description:

The Kaneka Trimotion™ Injector is indicated for insertion and placement of donor corneal tissue (diameter: ≤ 8.5 mm; thickness: 0.115-0.200 mm) into the anterior chamber of the recipient eye through a minimum 5.5 mm incision during a Descemet's Stripping with Automated Endothelial Keratoplasty (DSAEK) procedure.

The Kaneka Trimotion™ Injector is a single-use pen-shaped injector made of stainless steel and biocompatible plastics. It is used to fold, insert, and place donor corneal tissue by means of a major surgical procedure into a human eye during the Descemet's Stripping with Automated Endothelial Keratoplasty (DSAEK) procedure. Two color-coded sliding controls, called "pushers", are used to control the delivery of the donor tissue. Irrigation with intraocular irrigating solution and an air injection are applied through the device to aid in tissue delivery and placement. The system provides a tubular pathway through an

incision posterior to the cornea limbus, allowing delivery of the donor tissue into the human eye.

Substantial Equivalence:

The Kaneka Trimotion™ Injector is substantially equivalent to the Ocular System Inc. EndoSerter™ corneal endothelium delivery instrument as shown through an analysis of indications for use and the devices' technological characteristics.

	Kaneka Trimotion™ Injector (this 510(k))	**EndoSerter™ corneal endothelium delivery instrument (510(k) No. K090626)**
Indication	Insertion and placement of donor corneal tissue (diameter: ≤ 8.5 mm; thickness: 0.115-0.200 mm) into the anterior chamber of the recipient eye through a minimum 5.5 mm incision during a Descemet's Stripping with Automated Endothelial Keratoplasty (DSAEK) procedure.	To insert corneal endothelial allograft tissue measuring less than or equal to 8.5 mm in diameter and 175 micron in central thickness into the anterior chamber through a minimum 4 mm incision during endothelial keratoplasty procedures.
Operating Principle	The donor corneal tissue is loaded into the device and delivered into the human eye through an incision, then unfolded and placed at the desired position.	Same as proposed device.
Materials	Biocompatible plastics and metal	Biocompatible plastics
Mechanism	Co-axial tubes manipulated by 2 pushers	Spatula and sheath manipulated by thumbscrew and deployment wheels
Fluid path	Separate paths for balanced saline solution and air	Path for balanced saline solution only
Sterility Status	Supplied sterile	Same as proposed device.
Single Use?	Yes	Same as proposed device.

Discussion of Tests and Test Results:

The direct or indirect tissue contacting materials of the Kaneka Trimotion™ Injector have been subjected to biocompatibility testing. The results show that the device is biocompatible. The Kaneka Trimotion™ Injector has also been tested in a simulated use test that demonstrates the device to be effective for its intended use.

Conclusions Drawn from the Tests:

The tests provide evidence of the Kaneka Trimotion™ Injector's suitability for use in the DSAEK procedure and its substantial equivalence to the predicate device in terms of intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kaneka Corporation
c/o Mr. Tamiji Fujimoto
Manager, Regulatory Affairs
5-1-1, Torikai-Nishi, Settsu
Osaka 566-0072, Japan

DEC 2 9 2011

Re: K102999
Trade/Device Name: Kaneka Trimotion™ Injector
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I, reserved
Product Code: OTZ
Dated: December 19, 2011
Received: December 20, 2011

Dear Mr. Fujimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102999

Device Name: Kaneka Trimotion™ Injector

Indications for Use: The Kaneka Trimotion™ Injector is indicated for insertion and placement of donor corneal tissue (diameter: ≤ 8.5 mm; thickness: 0.115-0.200 mm) into the anterior chamber of the recipient eye through a minimum 5.5 mm incision during a Descemet's Stripping with Automated Endothelial Keratoplasty (DSAEK) procedure.

Prescription Use _XX_ AND/OR Over-the-Counter Use_____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K102999